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10/706,103	11/12/2003	Douglas Craig Scott	9118M2	5133

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

07/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/706,103

**Applicant(s)**

SCOTT ET AL.

**Examiner**

SHIRLEY V. GEMBEH

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- \_\_\_\_\_ Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- \_\_\_\_\_ Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/07 has been entered.

### **Response to remarks**

The response filed 10/19/07 presents remarks and arguments to the office action mailed 9/7/07. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

The following rejections and/or objections are either reiterated or newly applied.

### **Status of claims**

Claims 1-4 and 8-17 are pending.

Claims 5-7 are cancelled.

### ***Withdrawn Claim Objections***

Applicant amended the claims and the objection is moot with regards to the periods in the claims at the part designations "a.", "b.", "c." and "d." are improper.

### ***Withdrawn Claim Rejections - 35 USC § 112***

Applicant argument is persuasive, the rejection is withdrawn.

Claims 1-4 and 8-17 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for providing sustained delivery of an oral care activity active for at least 5 minutes, in the oral cavity of a subject in need thereof, does not reasonably provide enablement for preventing an oral condition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2)

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the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

In the instant case, Applicants are claiming in part, a method of preventing an oral condition in the oral cavity of a subject and promote whole body health thereof by providing sustained delivery of an oral active for at least 5 minutes.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth infra.

*The nature of the invention.* Applicant contemplates to use a composition comprising a water soluble particulate retentive agent, an oral care active agent, a surfactant and a buffer to treat or prevent any oral condition and to promote whole body health. However, the term "oral condition" is very broad and encompasses a large number of different diseases and conditions caused by different factors or are a result of different other disease such as diabetes, cancerous lesions, inflammatory vesiculoerosive changes and candidiasis such as musculoskeletal disorder, see entire references, Kelsey et al. (Abstract, Am. J. Public Health, 2008; 98(7) and Silverman, JADA vol. 138, 2007, 41S-46S. The invention discloses method of preventing an oral

condition in the oral cavity of a subject thereof by providing sustained delivery of an oral active for at least 5 minutes.

*The Predictability or Lack Thereof in the Art.* As discussed above prevention is not practical with oral diseases due to the unpredictability of the conditions involved. According to the American Dental Association ([http://www.ada.org/public/topics/bad\\_breath.asp](http://www.ada.org/public/topics/bad_breath.asp)), oral diseases can be caused by health problems (such as diabetes) or lack of getting the oral cavity professionally cleaned. Periodontal disease begins with plaque that is not removed during daily cleaning. When plaque is not removed it turns into calculus. It is impossible to remove all calculus with daily brushing ([http://www.perio.org/consumer/faq\\_general.htm](http://www.perio.org/consumer/faq_general.htm), pages 1-5). The calculus, if untreated, causes gingivitis, the first stage of periodontal disease. Therefore it is likely a small amount of gingivitis is present in between dental visits. In the case of the instant invention, periodontal disease can be caused by different factors, therefore it is nearly impossible to protect against them all with the claimed composition.

The art does not show how to prevent diseases as complex as cancer or diabetes and in the absence of such prevention, one of skill in the art would not understand how the composition would be used to prevent oral conditions. The specification does not provide such guidance.

*The Presence or Absence of Working Examples.* The examples in the specification are examples to the formulation of the composition and not to prevention. There is a lack of working examples showing the effect of the composition on patients that are vulnerable to such oral conditions/diseases or the effect of other conditions

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encompassed by the term "oral condition". The specification generally discloses a large number of agents but provides no example of such agents being used to prevent an oral condition or to promote whole body health.

In view of the absence of guidance in the art and the specification, one of skill in the art would require tremendous amount of undue experimentation to determine what agent if any could be used to prevent an oral condition or promote a whole body health.

The Lawlor reference is presented again in the 103 rejection

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 8-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor US 6,706,256 in view of Fine et al. US 4,374,822.

Lawlor teaches with regard to instant claim 1, a water insoluble particulate retentive agent as mica, zinc oxide, see col. 19, lines 22-40, an oral care active, (abstract), a surfactant (col. 18, lines 41-65), and a buffer (col. 22, lines 1-15) in the form of a chewing gum, a chewable solid unit, see col. 15, lines 21-65. Lawlor further teaches the composition maybe used in combination with brushing the teeth, (see col.24, lines 45-48).

Since, Lawlor teaches mica, zinc oxide (are identical to the claimed invention), they would necessarily have the same solubility of 1g/30g at 25° C or less than 1g/100g at 25°C as recited in claim 2.

With regard to claim 3, since Lawlor teaches the composition, one would expect the composition when chewed will be visible on 4-5 molar for 5-60 minutes. Additionally, Lawlor teaches the crunchy sensation remains consumer noticeable, therefore if the same agents as discussed above are chewed, one would expect them to be visible after 5mins because it is the agent that causes the crunchy sensation, (see col. 17, lines 25-31).

With regard to instant claim 4, Lawlor teaches a crunch sensation that is consumer visible, therefore, it is presumed that the agents will deposit at least 0.5%-20% of the weight of the initial composition on the tooth surface after chewing. See col. 17, lines 25-31).

Further Lawlor teaches with regard to claim 8 the oral active is selected from the group of anti-calculus agents, H2 antagonist etc, wherein the active agent the fluoride ion source provides from 100 ppm -1000 ppm range which encompasses the claimed range (see abstract and col. 11, lines 60-63) (claims 8-9). The buffer is selected is trisodium phosphate, see col. 22, lines 1-15. The reference also discloses that the solid unit is a compressed tablet. See col. 15, lines 30-31. Lawlor teaches the chewable dentifrices solid unit may be non-cariogenic (see col. 20, lines 43-55).

Lawlor fails to teach the percentage of the retentive particulate as 35-65% and is silent to the teaching of a non-effervescent.

It is for this reason that Fine et al. is joined.

Fine et al. teach dental oral composition such as chewable tablet, the water-insoluble polishing agent such as (magnesium carbonate) which is one of the claimed retentive particulate maybe present from 20-75%. See col. 3, lines 26-36. Fine does not teach mica, however, teaches the concept of varying the concentration of the water soluble agent to optimize the result.

It would have been obvious to one of ordinary skill in the art to modify the composition of Lawlor by varying the concentration of the retentive agent as taught by

Fine et al. with a reasonable expectation of success in employing the percentage of the water-insoluble polishing agent taught by Fine et al.

Therefore it would have been obvious to one of ordinary skill in the art to use the teachings and incorporate in the Lawlor disclosure to form oral dentifrices with 35-65% water-insoluble retentive particulate.

Although Lawlor is silent with respect to the presence of a non-effervescent one of ordinary skill in the art would have from the disclosure of the Lawlor that the dentifrices is non-effervescent because it contains the same agent as that in the claimed invention, therefore the same non-effervescent property is expected.

With respect to the limitation of a kit comprising (claim 12) the water insoluble particulate, selected from mica, magnesium carbonate, zinc oxide polyethylene powder etc having water solubility less than 1g/30g at 25 °C, an oral active a surfactant and a buffer, wherein the composition is a chewable solid unit dosage dentifrice is not innovative over the prior art; kits containing instructions for dental oral care have been used before the invention was made. One would have been motivated to assemble a kit, i.e., put the reagents in a box containing instructions how to use, because they are convenient to use and save time (see, US 5,772,986, col. 4, lines 30-35").

If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Claims 13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor US 6,706,256 in view of Fine et al. US 4,374,822 as applied to claims 1-4 and 8-11 above evident by Grossman et al. J. Dent. Res. 16(5), 409-416, 1937.

With regard to claim 13, since Lawlor teaches the composition, one would expect the composition when chewed or administered to the oral cavity the pH will be 7-12. Lawlor does not specifically teach buffering to a pH from 7-12 as recited (claim 13), however, the reference teaches composition that could be buffered to a pH of 10 (col. 22, lines 1-15). One of ordinary skill in the art by chewing the composition accompanied by brushing will raise the pH of saliva in the mouth. It is known to one of ordinary skill in the art that pH of saliva ranges from 5.0 to 8.0 with the average from 6.5-6.9, therefore having a pH of higher introduced in the mouth cavity will buffer the saliva to a higher pH. See as evidence by Grossman et al. J. Dent. Res. 16(5), 409-416, 1937, see entire document).

Since Lawlor teaches mica, zinc oxide, same as claimed invention, it is presumed that they will also have the same solubility of 1g/30g at 25° C or less than 1g/100g at 25°C as recited in claims 15 and 17.

With regard to instant claim 16, the same composition is already discussed above, although, Lawlor do not teach expectorating the slurry from the brushing, however, it is common to expectorate the slurry after brushing. One of ordinary skill in the art would have known that expectorating slurry after brushing is expected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

6/27/08